

Docket No.: 000166.0109-US02  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
David Edwards et al.

Application No.: Divisional of 10/268,059

Group Art Unit: N/A

Filed: February 5, 2004

Examiner: Not Yet Assigned

For: INHALATION DEVICE AND METHOD

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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO/SB/08a/b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c)

more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(i).

a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

4. Relevance of the non-English language document(s) is discussed in the present specification.

5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.

6. A concise explanation of the relevance of the non-English language document(s) appears below:

☒ 7. The Examiner's attention is directed to co-pending U.S. Patent Application Nos. 10/268,059, filed October 10, 2002 and 09/835,302, filed April 16, 2001, which are directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

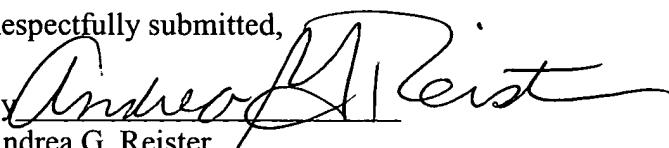
☒ 8. Copies of the documents were cited by or submitted to the Office in Application Nos. 10/268,059, filed October 10, 2002 and 09/835,302, filed April 16, 2001, which are relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 000166.00109-US02.

Dated: February 5, 2004

Respectfully submitted,

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|---------------------------------|---|----|---|--------------------------|---------------------------------|
| Substitute for form 1449A/B/PTO |   |    |   | <b>Complete if Known</b> |                                 |
|                                 |   |    |   | Application Number       | <b>Divisional of 10/268,059</b> |
|                                 |   |    |   | Filing Date              | February 5, 2004                |
|                                 |   |    |   | First Named Inventor     | David Edwards                   |
|                                 |   |    |   | Art Unit                 | N/A                             |
|                                 |   |    |   | Examiner Name            | Not Yet Assigned                |
| Sheet                           | 1 | of | 2 | Attorney Docket Number   | 000166.0109-US02                |

| <b>U.S. PATENT DOCUMENTS</b> |                       |  |                             |  |  |
|------------------------------|-----------------------|--|-----------------------------|--|--|
| Examiner Initials*           | Cite No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages or<br>Relevant<br>Figures Appear |
|                              |                       | Number-Kind Code <sup>2</sup> (if known) |                             |  |  |
| AA                           | US-3,635,219-B1       |  | 01/1972                     | Altounyan et al.                                   |  |
| AB                           | US-3,669,113-B1       |  | 06/1972                     | Altounyan et al.                                   |  |
| AC                           | US-3,795,244-B1       |  | 03/1974                     | Lax et al.   |  |
| AD                           | US-3,837,341-B1       |  | 09/1974                     | Bell   |  |
| AE                           | US-3,888,253-B1       |  | 06/1975                     | Watt et al.  |  |
| AF                           | US-3,906,950          |  | 09/1975                     | Cocozza  |  |
| AG**                         | US-4,013,075          |  | 03/1977                     | Cocozza  |  |
| AH                           | US-4,069,228          |  | 01/1978                     | Valentini et al.                                   |  |
| AI                           | US-4,069,819-B1       |  | 01/1978                     | Valentini et al.                                   |  |
| AJ                           | US-4,105,027-B1       |  | 08/1978                     | Lundquist  |  |
| AK                           | US-4,192,309          |  | 03/1980                     | Poulsen  |  |
| AL                           | US-4,240,418          |  | 12/1980                     | Roskamp et al.                                     |  |
| AM                           | US-4,860,740          |  | 08/1989                     | Kirk et al.  |  |
| AN                           | US-4,889,114-B1       |  | 12/1989                     | Kladders   |  |
| AO                           | US-4,995,285          |  | 02/1991                     | Valentini et al.                                   |  |
| AP                           | US-5,152,284-B1       |  | 10/1992                     | Valentini et al.                                   |  |
| AQ                           | US-5,239,992-B1       |  | 08/1993                     | Bougamont et al.                                   |  |
| AR                           | US-5,301,666-B1       |  | 04/1994                     | Lerk et al.  |  |
| AS                           | US-5,349,947          |  | 09/1994                     | Newhouse et al.                                    |  |
| AT                           | US-5,595,175-B1       |  | 01/1997                     | Malcher et al.                                     |  |
| AU                           | US-5,647,349          |  | 07/1997                     | Ohki et al.  |  |
| AV                           | US-5,651,359          |  | 07/1997                     | Bougamont et al.                                   |  |
| AW                           | US-5,673,686-B1       |  | 10/1997                     | Villax et al.                                      |  |
| AX                           | US-5,685,294          |  | 11/1997                     | Gupte et al.                                       |  |
| AY                           | US-5,727,546          |  | 03/1998                     | Clarke et al.                                      |  |
| AZ                           | US-5,740,794          |  | 04/1998                     | Smith et al.                                       |  |
| AA1                          | US-5,785,049          |  | 07/1998                     | Smith et al.                                       |  |
| AB1                          | US-5,797,391          |  | 08/1998                     | Cook et al.  |  |
| AC1                          | US-5,810,004          |  | 09/1998                     | Ohki et al.  |  |
| AD1                          | US-5,860,419          |  | 01/1999                     | Davies et al.                                      |  |
| AE1                          | US-5,896,855-B1       |  | 04/1999                     | Hobbs et al.                                       |  |
| AF1                          | US-5,921,237          |  | 07/1999                     | Eisele et al.                                      |  |
| AG1                          | US-6,089,228          |  | 07/2000                     | Smith et al.                                       |  |
| AH1                          | US-6,092,522-B1       |  | 07/2000                     | Calvert et al.                                     |  |
| AI1                          | US-6,102,035          |  | 08/2000                     | Asking et al.                                      |  |
| AJ1                          | US-6,116,237-B1       |  | 09/2000                     | Schultz et al.                                     |  |
| AK1                          | US-6,116,238-B1       |  | 09/2000                     | Jackson et al.                                     |  |
| AL1                          | US-6,142,145          |  | 11/2000                     | Dagsland et al.                                    |  |
| AM1                          | US-US 2003/0094173-A1 |  | 05-22-2003                  | Burr et al.  |  |

|                    |  |                 |  |
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| Examiner Signature |  | Date Considered |  |
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| Substitute for form 1449A/B/PTO<br><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |   |    |   | <b>Complete if Known</b> |                                |
| Sheet   | 2 | of | 2 | Application Number       | <b>Divisional f 10/268,059</b> |
|   |   |    |   | Filing Date              | February 5, 2004               |
|   |   |    |   | First Named Inventor     | David Edwards                  |
|   |   |    |   | Art Unit                 | N/A                            |
|   |   |    |   | Examiner Name            | Not Yet Assigned               |
|   |   |    |   | Attorney Docket Number   | 000166.0109-US02               |

| FOREIGN PATENT DOCUMENTS |                       |   |                             |  |   |                |
|--------------------------|-----------------------|---|-----------------------------|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                             |  |   |                |
|                          | BA                    | EA-0 407 276-A2   | 01/1991                     | VALOIS Societe Anonyme<br>dite                     |   |                |
|                          | BB                    | EP-0 506 292-A1   | 09/1992                     | Rhone-Poulenc Rorer Limited                        |   |                |
|                          | BC                    | WO-WO 94/08552-A2   | 04/1994                     | Mecikalski et al.                                  |   |                |
|                          | BD                    | WF-WO 00/64519-A1   | 11/2000                     | Haikarainen et al.                                 |   |                |
|                          | BE                    | WO-WO 01/07107  | 02/2001                     | Pharmaceutical Discovery<br>Corporation            |   |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                       |  |  |  |  |  |
|---------------------------------|-----------------------|--|--|--|--|--|
| Examiner Initials               | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  |  |  |  |  |
|                                 | CA                    | Bisgaard, H. et al., Fine particle mass from the Diskus inhaler and Turbuhaler inhaler in children with asthma, European Respiratory Journal, 11: 1111-1115 (May 1998).  |  |  |  |  |
|                                 | CB                    | de Boer, A.H. et al., "Inhalation characteristics and their effects on in vitro drug delivery from dry powder inhalers, Part 1. Inhalation characteristics, work on breathing and volunteers' preference in dependence of the inhaler resistance," International Journal of Pharmaceutics 130: 231-244 (1996). |  |  |  |  |
|                                 | CC                    | Dunbar, Craig A. et al., A Comparison of Dry Powder Inhaler Dose Delivery Characteristics Using a Power Criterion, PDA Journal of Pharmaceutical Science & Technology, 54(6): 4780484 (November/December 2000).  |  |  |  |  |
|                                 | CD                    | Feddah, Majid R. et al., In-Vitro Characterisation of Metered Dose Inhaler Versus Dry Powder Inhaler Glucocorticoid Products: Influence of Inspiratory Flow Rates, J. Pharm. Pharmaceut. Sci. ( <a href="http://www.ualberta.ca/~csp5">www.ualberta.ca/~csp5</a> ) 3(3): 317-324 (2000).                       |  |  |  |  |
|                                 | CE                    | Koskela, T. et al., Efficacy of salbutamol via Easyhaler® unaffected by low inspiratory flow, Respiratory Medicine 94: 1229-1233 (December 2000).  |  |  |  |  |
|                                 | CF                    | Nielsen, K.G. et al., Flow-dependent effect of formoterol dry-powder inhaled from the Aerolizer®, European Respiratory Journal, 10: 2105-2109 (September 1997).  |  |  |  |  |
|                                 | CG                    | Richards, Robert and Saunders, Michael, Need for a comparative performance standard for dry powder inhalers, Thorax 48: 1186-1187 (November 1993).   |  |  |  |  |
|                                 | CH                    | Ross, Danna L. and Schultz, Robert K., Effect of Inhalation Flow Rate on the Dosing Characteristics of Dry Powder Inhaler (DPI) and Metered Dose Inhaler (MDI) Products, Journal of Aerosol Medicine, 9: 215-226 (November 2, 1996).   |  |  |  |  |
|                                 | CI                    | Smith, Karen J. et al., Influence of Flow Rate on Aerosole Particle Size Distributions from Pressurized and Breath-Actuated Inhalers, Journal of Aerosol Medicine, 11: 231-245 (November 4, 1998).   |  |  |  |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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| Examiner Signature | Date Considered |  |
|--------------------|-----------------|--|